UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

RANDALL HIX, *et al.,*

Plaintiffs,

v.

ZIMMER BIOMET HOLDINGS, INC, *et al*.,

Defendants.

Case No. 3:18-cv-00437-RCJ-WGC

ORDER

In 2010, Randall Hix had an artificial hip replacement using a Biomet M2a Magnum implant. In 2012, the M2a Magnum implant was removed and replaced during a revision surgery, and Hix has had several surgeries on his hip since. Hix and his wife, Liana Hix, brought this suit against Defendants Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC, (collectively "Biomet") alleging the M2a Magnum artificial hip device was defective. (Amended Complaint, ECF No. 201). Presently before the Court is Biomet's Motion in Limine to exclude certain opinions by Hix's expert witness in biomedical engineering: Mari Truman, P.E. (ECF No. 270). Hix opposes the motion. (ECF No. 279). The Court will grant the motion in part and deny it in part.

I. PROCEDURAL HISTORY

On October 2, 2012, the Judicial Panel on Multidistrict Litigation transferred the first actions regarding Biomet M2a Magnum hip implants to the Northern District of Indiana as the Biomet M2a Magnum Hip Implants Products Liability multi-district litigation, MDL Case No. 3-12-md-2391. In

February 2013, the MDL court entered an order allowing parties to file new actions directly into the MDL action. In March 2014, Hix initiated this action by filing a complaint in the Biomet M2a Magnum MDL. Following consolidated pre-trial proceedings primarily directed to common-issue discovery and to some case-specific discovery, the MDL court transferred this matter to the District of Nevada in September 2018.

II. BACKGROUND

On July 12, 2010, Hix (then 36 years old) had a total hip arthroplasty (THA, i.e., joint replacement) performed by Dr. Richard Mullins. Dr. Mullins implanted the Biomet M2a Magnum metal-on-metal (MoM) artificial hip device.

Prior to the THA procedure, Hix had surgery in 1997 on his left hip due to a Slipped Capital Femoral Epiphysis when he was 13 years old.

In 2008, Hix began experiencing pain in his left hip that worsened over time. In March 2010, Hix was arthroscopically treated for left hip femoroacetabular impingement. When the procedure did not resolve Hix's pain, he was referred to Dr. Mullins, who recommended a total left hip replacement. Hix and Dr. Mullins met with a Biomet sales representative who demonstrated Biomet's sample hip prosthetics. Dr. Mullins thought that a metal-on-metal device would provide Hix a better quality of life – and would last longer – than a metal-on-polyethylene device. Hix decided to have the M2a Magnum MoM device implanted.

Following the THA procedure, Hix began again experiencing pain in his left hip in March 2012. He saw Dr. Suzanne Zsikla, who referred Hix to Dr. Richard Blakey, an orthopedic surgeon. Hix saw Dr. Blakey in August 2012. A radiograph was taken, showing the MoM implant with reactive bone at the end of the stem. A presumptive diagnosis of metallosis[1] was made.

[1] In his deposition, Hix's treating physician, Dr. Blakey, described metallosis as an inflammatory reaction to the wear product of an MoM device.

A bone scan performed on September 5, 2012, indicated Hix's hip was normal and did not indicate an abnormal uptake. On September 11, 2012, Dr. Blakey indicated he was fairly certain Hix did not have an infection and recommended a revision of the Biomet M2a Magnum MoM hip device.

Dr. Blakey performed the revision surgery on Hix's left hip on October 31, 2012. Dr. Blakey removed the Biomet acetabular cup and replaced it with a Zimmer metal-on-polyethylene constrained hip construct. He also removed damaged tissue and implanted a constrained liner to reduce the chance of dislocation or subluxation. Dr. Tony Yang examined the removed tissues for pathology and noted chronic inflammation, reactive hyperplasia, and pigmented macrophages containing a grayish pigment consistent with foreign material. Dr. Blakey's post-operative diagnosis noted painful left metal-on-metal total hip secondary to metallosis.

Two weeks after this surgery, Hix had an MRI of his lumbar spine, which showed an L5-S1 right-sided paracentral disc protrusion causing mild stenosis of the right neural foramina.

On January 10, 2013, Hix was seen by Dr. Blakey as Hix had "developed some cellulitis about the left hip wound." Dr. Blakey informed Hix that he might need to aspirate the hip. This procedure was performed on January 24, but produced "little fluid, if any." Cultures on the fluid were negative for infection. Hix was continuing to have pain when he had an office visit with Dr. Blakey in June 2013. Dr. Blakey "talked to [Hix] about the fact that sometimes the metallosis reaction comes back even though we have revised the hip." Dr. Blakey performed another left-hip aspiration in August 2013 and gave Hix a steroid injection.

Hix had a follow-up visit a week later. Dr. Blakey recorded in his notes: "I suspect that he is having continued inflammation, possibly from the metallosis." Following an office visit two weeks later, Dr. Blakey noted there was not much else he could do for Hix's pain.

Hix continued to have pain through 2014. In November 2014, Hix saw Dr. Martin Arraiz, who noted radiculitis (pain radiating along a nerve resulting from inflammation at the root of the nerve connecting to the spine) in the lower left extremity. Hix received an epidural injection in December 2014.

Hix saw Dr. Blakey in January 2015. Dr. Blakey noted Hix "is actually getting better with respect to his left hip. He is still having pain." Following a July 2015 office visit, Dr. Blakey noted "Hix has had increasing pain in his left hip revision last month."

On October 21, 2017, Hix went to the emergency room the day following "kicking an object . . . with his left leg" that resulted in "sudden onset pain left hip." The emergency doctor noted a final impression of "[p]ain of left hip joint" and "[d]islocation of left hip."

Two days later, Dr. Chad Watts performed a revision surgery on Hix's left hip for "failed constrained liner with dislocation of left total hip." Dr. Watts removed the cup with constrained liner and replaced it with a "62 Biomet OsseoTi shell with dual mobility liner" and "2B +6 revision ceramic head with a titanium sleeve." Dr. Watts notes indicate that Hix "was very scarred in and had a pretty stiff hip. There was some metal staining from his prior metallosis, but overall the muscle and tissues were in reasonable shape." He further noted the "constrained liner was broken – there had clearly been chronic impingement which led to failure."

Four weeks after the surgery, Hix visited the emergency room with "pain to the surgical site, redness, and drainage around surgical incision associated with fever (102.0 deg F) and chills." Hix underwent surgery the following day to open the surgical wound for "drainage with debridement and placement of wound VAC." Two days later, Dr. Robert Crouse performed another surgery. As Hix had "an obvious deep infection," Dr. Crouse removed the artificial hip devices, removed infected material for biopsy and culture, and performed a femoral osteotomy. Dr. Crouse further placed an antibiotic impregnated cement spacer in the acetabulum, the location of the infection. The material

removed for culture showed growth for Staphylococcus lugdunensis, with 1 of 3 cultures showing growth for Methicillin-Resistant Staphylococcus aureus. Hix remained on IV antibiotics for six weeks.

On February 8, 2018, Dr. Watts implanted an artificial hip consisting of a Stryker Restoration cup and stem with a ceramic head and cable.

Hix had an office visit with Dr. Ali Nairizi in June 2018 for pain management. Over the following year, Hix underwent a femoral nerve block, lumbar sympathetic nerve block, and SI joint injections with corticosteroids for pain.

In September 2019, Dr. Denis Patterson implanted a temporary dorsal root ganglion spinal cord stimulator for pain management and implanted a permanent stimulator the next month.

In November, Hix had an office visit with Dr. Watts, reporting a significant increase in pain and redness and swelling around the left hip. Dr. Watts recorded the impression of "[l]ikely infected left hip replacement." Dr. Watts aspirated the left hip. A culture of the withdrawn material indicated a streptococcus viridans infection. Hix underwent surgery on his left hip the following day, with Dr. Watts performing a tissue debridement and irrigation, and exchanging the MDM liner, the ceramic head and MDM head. On December 1, 2019, Dr. Watts performed another debridement and irrigation of the hip. Hix was hospitalized for the infected left hip from November 22, through December 11, 2019.

In May 2020, Dr. Patterson exchanged the implantable power generator for the nerve stimulator.

III. LEGAL STANDARDS

Federal Rule of Evidence 702 governs the admission of expert testimony and provides that if a witness is qualified as an expert by knowledge, skill, experience, training, or education, the witness can provide opinion testimony so long as:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The task of the trial court is to "assure that the expert testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" *Primiano v. Cook,* 598 F.3d 558, 564 (9th Cir. 2010) *quoting Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 597 (1993). This task applies to all expert testimony governed by Rule 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-148 (1999). Rule 702 "is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of [the relevant] discipline." *Daubert*, 509 U.S. at 592. The party offering the expert witness "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." Fed. R. Evid. 702 Advisory Committee Notes.

"[M]any factors will bear on the inquiry." *Daubert*, 509 U.S. at 593. In considering the admissibility of scientific expert testimony, the Supreme Court generally noted four factors while acknowledging that it was not setting "out a definitive checklist or test." *Id.* As summarized by the Ninth Circuit, a court may consider: "(1) whether the theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error and the existence of standards controlling a technique's operation; and (4) whether or not the theory is generally accepted." *United States v. Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000). However, these factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho*, 526 U.S. at 150.

Ultimately, the court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

IV. DISCUSSION

The Plaintiffs Steering Committee for the Biomet MDL retained Truman to provide generic or common issue expert testimony as a biomechanical engineer. Truman is a biomedical engineer with a B.S.E. in biomedical engineering and a master's degree in mechanical engineering. She holds nine patents for orthopedic devices; has experience designing devices and directing, analyzing, and performing testing of devices; worked for DePuy Orthopedics for 11 years, including as manager of hip and knee implant technology and senior product development engineer; and now serves as an associate at Robson Forensic.

In the MDL proceedings, Biomet moved to exclude Truman's opinions that: (1) all metal-on-metal devices are defectively designed; (2) metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices; (3) Biomet should have conducted additional testing of its metal-on-metal devices; (4) Biomet should have provided additional and more aggressive warnings to surgeons about the risks associated with its metal-on-metal devices; (5) Biomet downplayed the risks of its metal-on-metal devices; and (6) excessive metal ions cause certain clinical effects in patients with metal-on-metal devices.

The MDL court denied Biomet's motion, determining that Truman (1) was qualified to offer an opinion whether all metal-on-metal devices are defectively designed; (2) had considered sufficient facts to support her opinion that metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices; (3) was qualified to opine on the adequacy of medical device testing and had employed reliable methodology in forming her opinions on the adequacy of Biomet's testing; (4) that her experience developing and reviewing warnings for orthopedic products qualified

her to opine on the adequacy of Biomet's warnings and that her methodology to develop this opinion (comparing Biomet's warnings with relevant research on the alleged risks associated with metal-on-metal devices) was reliable; (5) that her opinions could help the jury understand the import and implications of the information and studies referenced in Biomet's materials and whether its marketing materials adequately captured the alleged risks described in the relevant scientific literature; and (6) that while Truman can't testify as an expert on the clinical effects of metal ions, she can permissibly rely on other experts' opinions that metal ions cause clinical effects to support her opinion that metal-on-metal devices are unreasonably dangerous.

A. Taper Corrosion

Biomet notes that large portions of Truman's report (including Appendix E) are devoted to issues related to taper corrosion and requests that these opinions should be excluded because Truman acknowledged that Hix did not have clinically significant taper corrosion and that she did not perform the tests to confirm the presence of taper corrosion. Hix responds by noting that Truman has not offered any opinions regarding taper corrosion as to Hix, but instead specifically noted that taper corrosion leading to clinical cold welding did not apply to Hix. The Court will deny Biomet's request to exclude Truman's opinions regarding taper corrosion because Hix has acknowledged, and Biomet has not shown otherwise, that Truman has not offered any opinion regarding taper corrosion applicable to Hix. The Court will, however, hold Hix to his representations that Truman will not be proffering opinions on taper corrosion or clinical cold welding.

The Court will also deny Biomet's request to generally exclude all opinions by Truman regarding corrosion. While Truman has acknowledged that she will not be offering an opinion on taper corrosion, such acknowledgement extends only to the extent of her statements concerning taper corrosion.

B. Undisclosed Common-Issue Opinions from New Material

Common issue non-expert discovery in the Biomet MDL was completed by December 26, 2016. Generic expert discovery ensued. Both plaintiffs and defendants filed *Daubert* motions, and the MDL court ruled on those motions in December 2017.

Biomet accurately notes that Truman's case-specific opinion report for Hix cites to material that pre-dates 2017. Biomet appears to then generally argue that the Court should exclude both new common issue opinions and existing common issue opinions that Truman has bolstered that are based on *any* new materials that Truman did not disclose in her original common issue report. The Court agrees that Truman cannot offer new common issue opinions, or bolster existing common issue opinions, with materials that were available to Truman prior to the common issue discovery cut-off of December 2016, but which she did not disclose in her MDL report. However, contrary to Biomet's implicit argument, Truman can permissibly rely on common issue discovery that first became available to Hix, and thus to Truman, after the close of common issue discovery. Specifically, pursuant to the MDL court's March 2020 order, Biomet was required to produce additional common issue discovery to the Plaintiffs' Steering Committee in the MDL. That additional common issue discovery consisted of discovery Biomet had produced in state court litigation after the MDL discovery deadline. This discovery necessarily consists of material that is "new" to Truman, that is, it first became available to her after she had prepared her MDL report.

While common issue discovery had closed in the MDL matter in December 2016, common issue discovery continued to take place in various state courts. Both state and federal courts issued orders preventing plaintiffs' counsel from sharing this additional common issue discovery material with other plaintiffs' counsel. However, Biomet voluntarily entered into private agreements with some federal plaintiffs to provide this additional common issue discovery, typically in an exchange resolving a discovery dispute. As the MDL court noted, this resulted in (a) attorneys for plaintiffs

in state courts having additional common issue discovery that they could use in their state cases; (b) attorneys with some clients in state court and some clients in federal courts who had access to additional common issue discovery because they represented state court clients but which additional material could only be used for the state court clients and not their federal court clients; (c) attorneys with some clients in state court and some clients in federal courts who received the additional material through the state cases and also received it in their federal cases through an agreement with Biomet; (d) attorneys with only clients in federal court who received the additional discovery through an agreement with Biomet; and (e) attorneys with only federal court clients who had not seen and lacked access to the additional common issue discovery.

In its March 2020 order, the MDL court noted that "[i]t seems unsatisfactory to a sense of justice that a state court plaintiff and a federal court plaintiff, with the same lawyer, the same allegedly defective product and the same cause of action should head into trial with different bodies of evidence – but at least the differing state and federal discovery rules provide an explanation." The MDL court went on to recognize, however, "[i]t's even more unsatisfactory if the difference stems not from different standards, or from different interpretations from different judges, but rather from the defendant's choice that one plaintiff will get evidence that another won't. That isn't a principal of the MDL process – or, for that matter, the American judiciary." The MDL court found this "situation is unacceptable." As relief, the MDL court ordered "Biomet to produce to the Steering Committee the extra generic discovery that it has already provided to state court plaintiffs." The Steering Committee could then provide this extra material to attorneys for federal plaintiffs.

Biomet argues that "[n]othing in the MDL Court's 2020 orders permitted additional disclosure of common issue expert opinions." The Court disagrees. The required disclosure of the additional generic discovery material necessarily permitted the additional disclosure of common issue expert opinions based on that newly provided material. Precluding plaintiffs, or their experts,

from relying on this extra common issue discovery produced pursuant to the MDL's March 2020 order would, effectively, eviscerate the entire purpose of that order. This Court will not construe the March 2020 order as requiring Biomet to disclose additional generic discovery to the federal plaintiffs while also precluding plaintiffs from being able to use that newly disclosed information.

In moving to exclude Truman's common issue opinions that Biomet asserts are newly formed (or that bolster an existing common issue opinion), Biomet has not attempted to distinguish whether the new material was provided pursuant to the March 2020 MDL order or was material that predated Truman's MDL report. Rather, Biomet has simply asserted that, because Truman confirmed that she generally relied on "new material" in making various opinions and statements, those opinions and statements should be excluded.[2] Regardless of whether Truman "confirmed" she relied on new material in her deposition, Biomet has not established that Truman relied on material that pre-dated her MDL report for any statement or opinion. Whether Biomet will be able to make such a showing, it has not done so in the present motion. Accordingly, the Court will deny Biomet's motion to the extent it seeks to exclude any new common issue opinions by Truman that are based on new material

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[2] The Court notes that Biomet asserts that Truman testified in her case-specific deposition that "everything discussed from pages 76-89 was new common-issue material *that was available prior to her MDL report*") (emphasis added). This is a mischaracterization of Truman's testimony, in which she agreed with defense counsel's representation that "everything that's contained in pages 76 to 89 is information that [Truman] received after [her] MDL report was prepared." As established by the Court's prior discussion, after Truman prepared her MDL report, she had access to, and could properly rely on, material that was NOT available to her prior to that report pursuant to the MDL court's March 2020 order. When counsel subsequently attempted to elicit testimony from Truman that she was relying on documents that existed prior to her MDL report, Truman responded, "As I said, I was just given the new information." Truman did not agree that the new information consisted solely of material that existed prior to her MDL report.

Further, even a cursory review of pages 76-89 establishes that many of Truman's statements in those pages rely upon material she could properly rely on pursuant to the MDL court's March 2020 order. For example, on page 78, Truman relies upon the deposition testimony of Mary Thacker and Angie Racolta. Page 6 of Truman's report notes that these depositions took place in January 2018 in the consolidated Florida cases. Biomet has not offered any argument that those depositions were not produced by Biomet to the Steering Committee pursuant to the March 2020 order.

(that is, the additional discovery produced to the MDL plaintiffs pursuant to the MDL Court's March 2020 order). The Court will also deny Biomet's motion to the extent it seeks to exclude Truman from relying on this new material to bolster previously disclosed common issue opinions. This decision is without prejudice to Biomet raising, at trial, appropriate and specific objections that Truman is offering a new common issue opinion, or has bolstered a previously disclosed common issue opinion, based on material that was available to Truman prior to the close of common issue discovery in December 2016.

C. Finding #3

In her deposition, Truman agreed that her Finding #3 in her case-specific report was poorly worded and did not make sense. Hix has not opposed Biomet's request to exclude this finding. The Court will exclude Truman's Finding #3.

D. Duty of a Reasonably Prudent Medical Device Manufacturer

In Finding #8 of her case-specific report, Truman starts with the statement that "[a] reasonably prudent medical device manufacturer has a duty to provide important safety information regarding the safety of their devices to the physicians who are using their product." Biomet seeks to exclude this statement as a legal opinion. Hix has not offered opposition. The Court will exclude Hix from using this statement from Truman's report.

E. Medical Causation Opinions

Biomet argues, and Hix does not dispute, that Truman is not qualified to opine on medical causation. The parties disagree, however, whether Truman has opined on (or simply recited the opinions of other expert's opinions on) medical causation in the case-specific report or whether she has appropriately relied on the expert opinions of doctors in forming her own biomechanical engineering opinions. Biomet identifies, as an example, Truman's statements in Finding #11, focusing on the first few sentences of that finding. Biomet asserts that Truman states that the device

implanted in Hix caused chronic pain and a limp which was the result of muscle tissue loss. The assertion mischaracterizes the first sentences of Finding #11. Truman does not, in Finding #11, attribute Hix's chronic pain and limp to the implanted medical device. Rather, she simply recites that Hix has chronic pain and a limp. Truman does state that Hix's "hip function was altered (made unstable) by the initial loss of muscle tissue due to the adverse tissue reactions to metal debris and corrosion product from his M2a Magnum MoM THA." Biomet labels this as a statement of medical causation. The Court disagrees that the statement is subject to such a straightforward and simple label, as it reflects a series of statements of causation: (1) muscle loss caused an unstable hip, (2) adverse tissue reactions caused muscle loss, (3) metal debris and corrosion product caused adverse tissue reactions, and (4) the implanted device caused the metal debris and corrosion product. Given the compound nature of the statement, and the lack of arguments by either party specifically directed to each component causation statement, the Court will not venture to provide an advisory opinion on the admissibility of either the statement as a whole or any of the constituent parts of the statement. Nor will the Court provide advisory opinions whether Truman's other statements in Finding #11 constitute impermissible medical causation opinions. Rather, the Court will grant Biomet's motion to the extent that Hix has not opposed it; that is: The Court will preclude Truman from offering medical causation opinions that simply recite or parrot the medical causation opinions of other experts. The Court will, however, allow Truman to rely upon medical causation opinions of other experts to the extent such opinions are properly admitted into evidence and to the extent that Truman can and has appropriately relied on those medical causation opinions to form her expert opinions.

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CONCLUSION

IT IS HEREBY ORDERED that the Motion in Limine to Exclude Certain Opinions of Mari Truman brought by Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC. (ECF No. 270) is GRANTED in part and DENIED in part as set forth above.

IT IS SO ORDERED.

Dated: March 29, 2022

ROBERT C. JONES
United States District Judge